IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO: *All cases listed in Exhibit A to Defendants' motion*	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE PEGGY PENCE, PH.D.

The Plaintiffs respectfully request that this Court deny Defendants' motion that seeks to exclude Dr. Peggy Pence's general opinions in their entirety or, in the alternative, certain general opinions.

INTRODUCTION

Peggy Pence, Ph.D., RAC, FRAPS ("Dr. Pence") is a specialist in medical device and pharmaceutical product development, regulatory affairs, and labeling standards for both medical devices and pharmaceuticals. Dr. Pence seeks to apply her extensive experience to assist the jury in understanding the complex regulatory requirements and industry practices which form the standard of care for a reasonable medical device manufacturer with regard to testing, labeling and post-market vigilance. Numerous courts have not only held that Dr. Pence is qualified to testify on these sorts of regulatory issues; but, have also commented favorably upon her impressive credentials. *See, e.g.*, *Huggins v. Stryker Corp.*, 2013 WL 1191058, at *18 (D. Minn. March 25, 2013); *Bonander v. Breg, Inc.*, 2012 WL 4128386, at *5 (D. Minn. Sept. 18, 2012); *Woodard v. Stryker Corp.*, 2012 WL 3475079 (D. Wyo. July 16, 2012); *Staub v. Breg, Inc.*, 2012

WL 1078335 (D. Ariz., March 30, 2012); *Musgrave v. Breg, Inc.*, 2011 WL 4543872, at *5 (S.D. Ohio, Sept. 29, 2011); *Schott v. I–Flow Corp.*, 696 F. Supp. 2d 898, 906 (S.D. Ohio 2010).

Despite these favorable rulings regarding Dr. Pence's testimony, Ethicon offers the traditional arguments against regulatory experts; namely, that Dr. Pence's testimony consists of narratives, legal conclusions, and irrelevant opinions. None of it is true. Dr. Pence has fulfilled her obligation as an expert to state the facts and data supporting her opinions. FED. R. EVID. 702. This Court has already considered, and rejected, similar challenges to the qualifications of a regulatory expert in the *Bard* MDL. In the *Bard* MDL, Defendant C.R. Bard, Inc. ("Bard") challenged the design, testing and labeling opinions of the plaintiffs' expert, Dr. David A. Kessler, on the ground that he had no medical experience implanting pelvic mesh devices and was not an engineer or urogynecologist. In finding Dr. Kessler qualified to offer labeling and testing opinions, this Court aptly observed that a witness may be qualified by "knowledge, skill, experience, training or education." *In re Bard, Inc. Pelvic Repair System Litigation*, 2013 WL 2432918, *30-31 (S.D.W.Va., June 4, 2013), *citing*, FED. R. EVID. 702. Just as Dr. Kessler's work experience afforded him a working knowledge of biomaterials that he discusses in the context of the regulatory process, Dr. Pence's extensive professional experience affords her a general understanding of how medical issues interact with the regulatory process. It is that expertise which Dr. Pence seeks to share with the jury.

Dr. Pence's more than forty years of experience on the industry side of the regulatory process allows her to inform the jury regarding industry practices. Because Dr. Pence's testimony is methodologically sound and would assist the jury in understanding the complex regulatory obligations of a device manufacturer, it should be admitted into evidence. Moreover, Dr. Pence can and has testified in cases where evidence of FDA clearance was excluded by the

Court as Dr. Pence relies on industry standards, not just FDA regulations and guidance in forming her opinions.[1] This point distinguishes Dr. Pence from Timothy Ulatowski, the Defendants' regulatory expert, whose opinions are all tied directly to the FDA, as described in the motion to exclude his testimony. Ethicon's motion to exclude Dr. Pence's testimony should be denied.

BACKGROUND

Dr. Pence is a Ph.D. toxicologist, scientist, and pharmaceutical and medical device product development, clinical studies, and regulatory affairs specialist.[2] She has decades of relevant experience in the medical device and pharmaceutical industries, has received numerous regulatory professional accolades, and has extensive toxicology, pharmacology, and continuing regulatory education and training. She has earned peer-reviewed certification of the Regulatory Affairs Professional Society ("RAPS"),[3] based on her professional experience, credentials, and training. Beyond being RAPS certified, Dr. Pence is also a RAPS Fellow.[4] More specifically, Dr. Pence has:

(i) Nearly 40 years of combined experience in the research and development of drug, biotech, and medical device products. She has worked on regulatory and project development matters as an employee of Eli Lilly, Serono Laboratories, Triton Biosciences, and Amgen. With each, she was responsible for

[1] *See* Exhibit H., Motion in Limine 5 and 9, *Batiste v. McNabb,* No. DC-12-14350. *See Also,* Exhibit I., Order (transcript) Granting Motions in Limine 5 and 9 *Batiste v. McNabb,* No. DC-12-14350, which prohibited Ethicon and Johnson & Johnson from introducing evidence referring to the FDA having approved or cleared the TVT-O device, and any evidence related to clearance and/or lack of enforcement regarding the TVT-O device. Despite the exclusion of this evidence, Dr. Pence was still able to offer testimony regarding standards on medical device labeling and testing, and opinions regarding whether or not Ethicon and Johnson & Johnson complied with those standards with regard to the TVT-O device.

[2] Exhibit B., Pence CV

[3] RAPS is the leading international organization for regulatory professionals working to ensure the safety, efficacy, and availability of healthcare products, including medical devices, pharmaceuticals, and biotechnology.

[4] The program recognizes professionals with over 15 years of experience for their significant contributions and leadership. RAPS Fellows, *available at* http://www.raps.org/membership-amp-benefits/raps-fellows.aspx (last visited May. 7, 2016).

preparing documents for FDA review, clinical data, and/or interfacing with the FDA on regulatory and quality.

(ii) Over fifteen years as Founder, President, and CEO of Symbion Research International, a full-service contract research organization offering clinical research services for conducting clinical studies, clinical trials, and regulatory and clinical development services for pharmaceuticals and medical devices. Summarily, Dr. Pence manages the complex development process for its pharmaceutical and medical device companies.

(iii) Experience working with more than 70 companies and over 85 drugs and medical devices, including advising companies concerning applicable standards, preparing and submitting regulatory documents to FDA such as 510(k) applications, and serving as the U.S. Agent or authorized representative for FDA matters.[5]

Because Dr. Pence's testimony is methodologically sound and would assist the jury in understanding the complex regulatory obligations of a device manufacturer, it should be admitted into evidence. Ethicon's motion to exclude Dr. Pence's testimony should be denied.

LEGAL STANDARDS

Federal Rule of Evidence 702 sets forth the basic framework for analyzing the admissibility of expert opinions. The rule reads, in pertinent part, as follows:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702.

If the witness is suitably qualified, then the *Daubert* inquiry generally breaks down into a two-step analysis. The first issue is whether the proffered evidence represents "scientific knowledge," meaning that it is supported by appropriate validation. The second issue is whether the evidence would assist the jury. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995).

[5] Exhibit B, Pence CV

This aspect of the inquiry is often discussed in terms of whether the expert's opinions "fit" the case. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591-92 (1993).

ARGUMENT

Defendants have moved to exclude Dr. Pence's testimony in the entirety, but have also offered six specific areas of testimony which they request be excluded. Many of the arguments use the same circular logic and reasoning to the point where it is difficult to distinguish the arguments from each other. Plaintiffs will respond point-by-point, as best it can be done with the overlapping arguments and material.

I. Dr. Pence is well qualified to opine about the adequacy of the device IFU's, and her methodology is reliable and admissible.

As discussed above, Dr. Pence is well qualified to offer opinions regarding the adequacy of the device IFU's. Since the majority of Defendant's brief focuses on Dr. Pence's methodology rather than her qualifications and credentials, there will be no further discussion of Dr. Pence's qualifications here.

Section 501 of the FDCA deals with misbranding of medical devices. A medical device is misbranded if its labeling is "false or misleading" in any particular manner. FDCA § 502A. A medical device is also misbranded if its labeling does not bear adequate warnings. FDCA § 502(f)(2). Thus, prescription medical devices, such as the TVT, TVT-O, Prolift, and Prosima (hereinafter, "Mesh Products") must include information regarding indications, contraindications, side effects and precautions ,which are necessary to allow physicians to administer the device safely.[6]

[6] Ex. A., Device Labeling Guidance #G91-1 (Blue Book Memo), FDA office of Device Evaluation, Mar. 8, 1991. *See also*, Ex. C., Final Document: Global Harmonization Task Force. Essential principles of Safety and Performance of Medical Devices, November 2, 2012 (revision of GHTF/SG1/N41:2005).

Ethicon first criticizes Dr. Pence's methodology in reaching her conclusions that the labels for the Mesh Products are inadequate because she "does not account for what physicians already know." However, Defendants cite to no applicable standard which would allow a device manufacturer to omit risk information from a medical device IFU based on what physicians already know. In fact the relevant standards require the device manufacturer to:

> Describe serious adverse reactions and potential safety hazards, limitations imposed by them, and steps that should be taken if they occur. Include an appropriate warning if there is reasonable evidence of an association with the use of the device. A causal relationship need not have been proved.[7]

There is nothing in any regulation, guidance, or industry standard that allows a device manufacturer to omit a warning or adverse event based the fact that doctors may already know about the risk. Moreover, it does not comport with the testimony of Ethicon's own medical director, who testified that physicians should be able to rely on the IFU to accurately disclose the risks associated with the use of the mesh product.[8]

Next, Defendants attack Dr. Pence for considering GHTF guidelines, claiming that she relies on them *post hoc*. This is simply not the case. The Global Harmonization Task Force (GHTF) was conceived in 1992 to address the growing need for international harmonization in the development of medical devices with two principle aims: (i) enhancing patient safety, and (ii) increasing access to safe, effective and clinically beneficial medical technologies worldwide.[9] During its approximately 20-year existence, GHTF was a partnership between medical authorities and was comprised of five founding members, including members in the United

[7] Ex. A., Device Labeling Guidance #G91-1 (Blue Book Memo), FDA office of Device Evaluation, Mar. 8, 1991. Section V.
[8] Exhibit. D., Testimony of David Robinson, March 14, 2012; 488:11-18. Dr. Robinson was specifically testifying about the Prolift IFU, but in his capacity as medical director, also had oversight for the TVT, TVT-O and Prosima products.
[9] Global Harmonization Task Force Archive Website: http://www.imdrf.org/ghtf/ghtf-archives.asp

States.[10] Defendant's own brief recognized that his Court has said that Dr. Pence would be allowed to testify to GHTF standards in some contexts in 2015, which means that Dr. Pence's reliance on GHTF cannot be *post hoc* as she has necessarily reviewed and relied upon those standards before her opinions were issued in this case.[11] Dr. Pence has acknowledged that there are standards other than FDA regulations on which experts can rely, and had incorporated those standards as a basis for her opinions, which is exactly what an expert following sound methodology should do.

Finally, Defendants attack Dr. Pence's opinion that both the Blue Book Guidance issued by the FDA and the GHTF guidance require that the IFU warn of the frequency and severity of the risks. However, this is exactly what Defendants did when they updated the TVT IFU in April of 2015.[12] Ethicon specifically added chronic pain, pain with intercourse which in some patients may not resolve, chronic pain in the groin, and one or more revision surgeries may be necessary to treat these adverse reactions to the IFU, among numerous other additions to the adverse reactions section. Defendants also incorrectly assert that the GHTF standards contain no standard requiring users of the frequency of risks.[13] The standards specifically state that a device manufacturer should inform users of any residual risks,[14] and specifically defines risk as a "combination of the probability of occurrence of harm and the severity of that harm."[15] Thus, the Defendants' brief is factually incorrect in that regard. Therefore, Dr. Pence is correct and has

[10] Ex. C, Final Document: Global Harmonization Task Force. Essential principles of Safety and Performance of Medical Devices, November 2, 2012 (revision of GHTF/SG1/N41:2005).
[11] *See* Defendant's memorandum at 6, citing *Mathison v. Boston Scientific Corp*., 2015 WL 2124991, *14)S.D. W. Va. May 6, 2015).
[12] Exhibit. G., TVT IFU issued 05-2015.
[13] Def. Memorandum at 9
[14] Ex. C, Final Document: Global Harmonization Task Force. Essential principles of Safety and Performance of Medical Devices, November 2, 2012 (revision of GHTF/SG1/N41:2005). Page 9.
[15] *Id*. at 8.

applied reliable methodology in stating that industry standards require consideration of the frequency and severity of the risk in the product labeling of a medical device.

For these reasons, the Court should reject Defendants' first argument.

II. Dr. Pence is well qualified to opine that Ethicon did not meet the post-market vigilance standard of care for the Mesh Products, her opinion is relevant and her methodology is reliable.

Medical device manufacturers have an obligation, under the Medical Device Reporting ("MDR") regulations, to report to the FDA all suspected adverse incidents involving their medical devices. 21 U.S.C. § 360i(a)(1); 21 CRF Part 803. An "MDR Reportable Event" occurs whenever a manufacturer learns of anything "reasonably suggest[ing]" that its device: (1) "[m]ay have caused or contributed to a death or serious injury," or (2) experienced a non-injurious "malfunction" that "would be likely to cause or contribute to a death or serious injury" if it recurred. 21 C.F.R. § 803.50(a). MDR reports submitted to FDA are entered into the Manufacturer and User Facility Device Experience ("MAUDE") database. The MDR program is important because it allows the FDA and manufacturers to identify and monitor significant adverse events so as to detect and correct safely problems with the device.

a. Dr. Pence is qualified to offer an opinion on whether an adverse event should have been reported to the FDA.

As Dr. Pence has explained, a manufacturer can withhold a report if it has "information that would lead a person who is qualified to make a medical judgment reasonably to conclude that a device did not cause or contribute to a death or serious injury." 21 CFR 803.20(c)(2).. Section 803.20(c)(2) expressly states that "persons qualified to make a medical judgment" include not only physicians but "nurses," "biomedical engineers" and "risk managers." *Id.*

Dr. Pence has functioned as a risk manager for "years and years" of her career.[16] Indeed, Dr. Pence explains that her professional work involves reviewing adverse event data and determining whether MDR reports should be submitted to the FDA.[17] Thus, Dr. Pence was able to apply the same standards in arriving at her opinion as to the reportability of TVT reports as she regularly applies when making the same determinations for her clients.[18]

Simply stated, Dr. Pence does not require a medical degree to offer an opinion on whether an event is outside of the MDR reporting requirements. Dr. Pence has medical and scientific knowledge as a toxicologist and as a clinical development regulatory scientist that she was able to apply to issue reports in the context of the MDR reporting regulations.[19]

b. Dr. Pence's testimony regarding Ethicon's failures to submit required MDR reports is relevant and reliable.

Dr. Pence's opinion that Ethicon failed to comply with post-marketing vigilance standards is reliably derived from her experience and applies regulatory standards to existing facts. Here, Dr. Pence has thoroughly explained the reporting requirements applicable to MDRs. In particular, Dr. Pence explains that a manufacturer is obligated under the FDA regulations to report to the FDA any information reasonably suggesting that its device either (1) caused or contributed to a death or serious injury, or (2) malfunctioned in a manner that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.[20] After applying these regulatory standards to the Issue Reports received by Ethicon, it is Dr. Pence's expert opinion that Ethicon failed to report to the FDA events that were MDR reportable.

[16] Exhibit. E. Transcript of Dr. Pence's November 11, 2013 deposition, 228:6-9
[17] *Id*. at 226:1-7; 228:1-5
[18] *Id*. at 228:6-15
[19] *Id*. at 228:24-229:4
[20] Def. Ex. D. Dr. Pence's TVT Report, Oct. 14, 2013

In support of her opinion that Ethicon failed to file required MDR reports, Dr. Pence noted that Ethicon submitted only 70% of the issue reports it received to the FDA as MDR Reports. [21] Meanwhile, Ethicon withheld approximately 30% of the Issue Reports from the FDA under the rationale that they were "not reportable."[22] After a review of non-submitted reports, Dr. Pence offered thirty-nine examples of adverse events that fit the regulatory reporting criteria but that were not submitted to the FDA as MDRs by Defendants.[23] Importantly, Ethicon does not find fault with Dr. Pence's methodology in evaluating the seven expansively detailed incidents as "reportable." Instead, Ethicon dickers only with Dr. Pence's characterization of the seven incidents detailed in her Report as being "representative" of the rationale's applied by Ethicon in the other thirty-two instances. Even if Ethicon were correct and thirty-two of the thirty-nine identified cases were not reportable for reasons akin to those in the seven highlighted incidents (which is not the case), this sort of quibbling over the underpinnings of Dr. Pence's opinion go to the weight for the expert's opinion- but not to the opinion's admissibility. *Jones v. Otis Elevator Co.*, 81 F.3d 655, 663 (11th Cir. 1988). At most, the number of unreported MDR's may factor into the weight the jury chooses to give to Dr. Pence's opinion regarding failures of post-marketing vigilance; but, it does not negate the opinion's admissibility.

c. Dr. Pence's testimony regarding Ethicon's failures to submit required MDR reports is relevant.

The purpose of the MDRs is to enable the FDA to have a complete picture of the safety profile for products.[24]. As the CDRH Director, Office of Compliance, Timothy Ulatowski has explained, MDR reports are the principle method used to assimilate product information and take

[21] *Id.*
[22] *Id.* at 174:15-16
[23] Def. Ex. D. Dr. Pence's TVT Report, Oct. 14, 2013
[24] Ex. E. Transcript of Dr. Pence's November 11, 2013 deposition; 186:22-24

action.[25] The FDA depends on manufacturers' compliance with MDR reporting requirements so that the Agency can perform its work in post-market surveillance and in identifying potential safety signals. In other words, compliance with the MDR reporting regulations is necessary to the protection of the public's health. The MDR requirement does not exist to cause manufacturer's busy work and is critical to ensuring the safety of medical devices.

d. Ethicon's mischaracterizations of Dr. Pence's testimony do not render that testimony inadmissible.

Ethicon's argument that Dr. Pence is offering improper legal conclusions misunderstands both the nature of Dr. Pence testimony and the law.[26] Dr. Pence is not offering a legal conclusion. Dr. Pence is merely informing the jury of the FDA regulations that form the medical device industry's standard of care, and then applying her expertise to opine whether Ethicon complied, or failed to comply, with those standards. Numerous cases hold that an expert may opine as to whether the defendant violated the standard of care in fields where specialized knowledge is necessary to understand the defendant's particular obligations.[27] *E.g. Grossman v. Barke*, 868 A.2d 561, 566 (Pa. Super. Ct. 2005) (when a claim "encompasses matters not within the ordinary knowledge and experience of laypersons ... [a] plaintiff must present expert testimony to establish the applicable standard of care [and] the deviation from that standard. . ."); *Holbrook v. Woodham*, 2007 WL 2071618 (W.D. Pa., July 13, 2007)(whether a

[25] Exhibit J. Ulatowski,TA., Risk Management: A Regulatory Perspective, Presentation, Beijing, October 2008

[26] To the extent that Ethicon's argument could be read as asking the Court to exclude broad swaths of unspecified testimony as "legal opinions," this Court should decline such request. *In re Levaquin Prod. Liab. Litig.*, MDL No. 08–1943, 2010 WL 4676973, at *3 (D. Minn. Nov. 9, 2010) ("Motions that lack specificity and are 'essentially repetitive of well-established rules of evidence' are not generally granted."); *Metzger v. American Fidelity Assur. Co.*, 2007 WL 4342082, *3 (W.D. Okla., Dec. 07, 2007)(declining to exclude expert testimony as a legal conclusion where the moving party did not set forth what specific testimony it sought to exclude).

[27] Indeed, a "witness may properly be called upon to aid the jury in understanding the facts in evidence even though reference to those facts is couched in legal terms." *Peckham v. Con'l Cas. Co.*, 895 F.2d 830, 837 (1st Cir. 1990); *First Nat'l State Bank of N.J. v. Reliance Elec. Co.*, 668 F.2d 725, 731 (3rd Cir. 1981).

defendant failed to comply with applicable safety regulations and industry codes are questions that will necessitate expert testimony because lay jurors do not commonly understand such professional obligations). *See, e.g.*, *Grossman v. Barke*, 868 A.2d 561, 566 (Pa. Super. Ct. 2005) (when a claim "encompasses matters not within the ordinary knowledge and experience of laypersons ... [a] plaintiff must present expert testimony to establish the applicable standard of care [and] the deviation from that standard. . ."); *Holbrook v. Woodham*, 2007 WL 2071618 (W.D. Pa., July 13 2007) (whether a defendant failed to comply with applicable safety regulations and industry codes are questions that will necessitate expert testimony because lay jurors do not commonly understand such professional obligations). *See also Peck v. Horrocks Engineers, Inc*., 106 F.3d 949 (10th Cir. 1997) (expert testimony is needed to establish a specialized standard of care and to assess whether that standard has been breached).

Understanding the FDA regulations that set the standards for the medical device industry, and determining the facts which are significant in identifying whether that standard was met, requires specialized knowledge and experience. *In re Fosamax*, 645 F.Supp.2d at 19, *see also Reese, LP*, 500 F.Supp.2d at 744; *Lellebo v. Zimmer, Inc.* 2005 WL 288596, at *5 (D. Minn. 2005). Without Dr. Pence's testimony, the jury would be left to determine whether Ethicon acted as a reasonable pharmaceutical company without any guidance as to the governing regulations and industry standards or any assistance in determining which medical events or information was pertinent to that determination.

Defendants' claims that Dr. Pence's opinions about failure to submit a 510(k) notification with regard to the Prolift have no relevance are belied by the fact that Ethicon wants to present evidence that the Prolift was (eventually) cleared by the FDA. However, for the following reasons, Defendant's argument does not warrant exclusion of evidence that Defendants fell

below the industry standard of care prior to marketing the Prolift. Evidence regarding compliance with industry standards and regulations is relevant to Plaintiff's negligence claim and request for punitive damages. *Horne v. Owens–Corning Fiberglas Corp.*, 4.F.3d 276, 281 (4th Cir. 1993) (Evidence of industry standards as well as noncompliance with, or nonexistence of, internal testing procedures are admissible in products liability cases). Expert testimony addressing compliance or non-compliance with industry standards and regulations can assist the jury in determining whether a defendant acted as a reasonably prudent manufacturer. *Lemons v. Novartis Pharmaceuticals Corp.*, 2012 WL 965977, at *5 (W.D.N.C. Mar. 21, 2012) ("Certainly, where labeling of a pharmaceutical product is at issue, [expert regulatory] testimony will assist the trier of fact in understanding the complexity of the FDA's regulatory scheme and the role of [the defendant] in complying with that regulatory scheme."); *Fosamax*, 645 F. Supp. 2d at 190-91 n.16 (holding that an expert (1) "may offer testimony embracing an ultimate issue of fact that the jury will decide" and (2) "is permitted to draw a conclusion from a set of observations based on extensive and specialized experience," including conclusions about a manufacturer's conduct); *Lillebo v. Zimmer, Inc.*, 2005 WL 388598 (D. Minn. Feb. 16, 2005); *In re Gadolinium-Based Contrast Agents Prods. Liab. Litig.*, 2010 WL 1796334 *12-14 (N.D. Ohio May 4, 2010) (permitting plaintiffs' regulatory expert to testify regarding general FDA regulatory requirements and procedures and offer her opinion, based on the regulatory framework and her analysis of the evidence, as to whether defendant complied with regulatory requirements).

If nothing else, Dr. Pence's opinions are relevant to rebut the Defendants' claims that they acted as a reasonable manufacturer in marketing the Prolift device, if Defendants are allowed to introduce evidence that the device was ultimately cleared. Moreover, Dr. Pence's opinions that Ethicon should have submitted a 510(k) for the Prolift prior to marketing the device in 2005 are

consistent with the opinions of the FDA's own reviewers, who told Ethicon exactly that in 2007.[28]

For these reasons, the Court should reject Defendants' second argument.

III. Dr. Pence is qualified to offer opinions about the adequacy of the Mesh Products testing.

A common criticism of the 510(k) clearance process is that it fails to impose firm and rigorous standards for testing and labeling medical devices. Yet, the absence of specific and detailed testing requirements as a condition for clearance to market the device does not mean that a manufacturer can neglect all testing of its product. To the contrary, a medical device manufacturer must still conform its testing practices to the standards of a reasonable manufacturer in the medical device industry. Thus, the customs and practices of an industry are proper subjects for expert testimony." *Pelletier v. Main St. Textiles, LP*, 470 F.3d 48, 54–55 (1st Cir. 2006). Indeed, the customary practices of industry members are recognized as a factor that the jury may consider in evaluating strict liability and negligence claims. *Bartlett v. Mutual Pharmaceutical Co., Inc.*, 742 F.Supp.2d 182, 188 (D.N.H., 2010).

As a forty-year veteran of the regulatory process who is experienced from the manufacturer's perspective, Dr. Pence is uniquely qualified to opine about the factors and considerations that go into a manufacturers' decisions as to what testing is necessary and appropriate. The committee notes to Rule 702 expressly contemplates that an expert may be qualified on the basis of experience, and that an expert's experience may be "the predominant, if not sole, basis for a great deal of reliable expert testimony." FED. R. EVID. 702, advisory committee notes (2000). Consistent with Rule 702's directive, an expert who had worked for

[28] Exhibit. F. Correspondence from FDA to Ethicon, August 10, 2007

three major drug companies and the FDA was permitted to testify about the standards of care in the medical industry. *Bartlett*, 742 F. Supp. 2d at 195. The foundation for that testimony was the expert's own experience. *Id.; see also Forrestal v. Magendantz*, 848 F.2d 303, 308 (1st Cir.1988) (affirming admission of doctor's expert testimony "based on his own knowledge and experience").

That same sort of testimony – reliably grounded in years of professional experience as an industry insider – is what Dr. Pence seeks to share with the jury in this case. Dr. Pence is able to call upon her extensive experience to inform the jury how known information regarding persistent FBR, chronic inflammation, mesh degradation and cytotoxicity (among other things) is viewed by a reasonable medical device manufacturer when considering whether and what testing to perform on its product. Through her experience developing drugs and devices and bringing them to market, Dr. Pence is able to inform the jury that the practice within the medical device industry is to consider what is known about the product and its components and predicates, to look at the existing medical literature regarding the product or similar products, and to assess what additional information needs to be obtained through testing to determine if the product is safe for its intended use. This methodology is the same one employed by Dr. Pence when advising medical companies regarding the testing needed to bring their products to market.

Dr. Pence has stated, and Defendants have acknowledged, that she relies, on part, in GHTF standards which state "clinical data can be in the form of scientific medical literature and commercial experience as well as clinical studies."[29] That Ethicon might prefer a different standard and disagree whether there is enough available literature to establish a favorable risk-benefit profile are issues that goes to the weight of the evidence, not to the testimony's admissibility. *Kellogg v. Wyeth*, 2012 WL 2970621, (D. Vt. July 20, 2012) (complaint that

[29] Def. Memorandum at 13, citing Pence 3-9-16 Dep. Tr. 75:8-11; Def. Ex. H.

expert's testimony regarding the industry standard of care for pharmaceutical labeling was not adequately grounded in objective regulatory standards went to the weight of the evidence but not its admissibility). Likewise, Ethicon's internal standards acknowledge the manufacturer's responsibility for the safety of the persons using its products, which confirms the presence of an industry standard beyond the minimal testing requirements of the 510(k) process.

Dr. Pence's testing opinions are based on specific industry standards and supported by reliable methodology. Accordingly, the prior decisions by this court cited by Defendants to exclude failure to test opinions does not preclude a decision in this case to admit testing opinions from Dr. Pence which rely on specific, articulable industry standards, as well as Ethicon internal standards. While the defendants may disagree vehemently with Dr. Pence's conclusions, that does not make them inadmissible.

IV. Dr. Pence's Opinion that the Mesh Products' labeling did not support adequate consent are relevant and admissible.

This argument by Defendants seems to be largely cumulative of arguments offered by Defendants that Dr. Pence is not qualified to opine about what warnings Ethicon should place in the product IFU. The fact that Dr. Pence is not a surgeon or medical doctor does not mean she has no expertise regarding what additional information physicians need to adequately consent their patients.[30] Dr. Pence's opinions in this regard are rooted in industry standards, which set forth what is required to be in an IFU, as well as her experience as a risk manager. As doctors are the intended audience for the IFU, it logically follows that FDA and industry guidance regarding the content of the IFU is designed to inform doctors of the risk of the device and the procedure, so they can pass that information on to their patients. Lastly, Ethicon objects to this opinion as

[30] As noted previously, 21 CFR 803.20(c)(2).. Section 803.20(c)(2) expressly states that "persons qualified to make a medical judgment" include not only physicians but "nurses," "biomedical engineers" and "risk managers."

either a) cumulative, or b) seeking to inject irrelevant issues into the case. To the extent that Ethicon objects to the opinions of Dr. Pence as cumulative, that is a matter of trial management, not a basis for ruling Dr. Pence's testimony inadmissible prior to trial. Plaintiffs are aware of no case, and Ethicon has cited none, where an expert's otherwise relevant and reliable testimony was ruled inadmissible at the pre-trial stage because it overlapped with other expert testimony that had not yet even been presented to the jury. On the issue of relevance, The risks attendant to the Mesh Products is relevant to the physician and patient's risk analysis, the patient's right to make an informed decision regarding their care, and to the question of whether Ethicon complied with the standard of care required of a reasonably prudent manufacturer when supplying warnings about its product.

V. Dr. Pence's opinion that Ethicon obtained clearance to market the Prosima based on false or misleading statements to the FDA is based relevant and admissible.

A 510(k) requires a truthful and accurate statement to be submitted and signed by an employee of the sponsor. 21 CFR § 807.87(k). This states in relevant part: "I certify that in my capacity as (the position held in the company) of (company name), I believe to the best of my knowledge that all data and information submitted in the premarket notification are truthful and accurate and no material fact has been omitted." *Id*. The key part of this requirement is that no material fact can be omitted from the 510(k). Whether or not the Defendant omitted material facts to the FDA regarding the Prosima device or other Mesh Products in its 510(k) application is relevant to the question of whether or not Ethicon acted as a reasonable manufacturer when marketing the Mesh Products. Dr. Pence is not offering an opinion as to whether or not Defendants broke the law or trying to enforce the FDA's regulatory scheme; she is merely articulating the industry standard that no material information be omitted from an application to

market a medical device, then articulating how defendants deviated from that standard, and offering an opinion on the likely result if defendants had complied with that standard.

Dr. Pence's opinion that the Prosima would not have been cleared by the FDA if the FDA had different or additional information is not sheer speculation; rather, it is Dr. Pence's opinion supported by her more than 40 years in the medical device industry, and is supported by reliable methodology. The mere fact that Defendants disagree with Dr. Pence's conclusion does not make the opinion inadmissible. An expert witness may properly testify about or comment on any documents and exhibits in evidence, and may explain "the regulatory context in which they were created, defining any complex or specialized terminology, or drawing inferences that would not be apparent without the benefit of experience or specialized knowledge." *Fosamax,* 645 F. Supp. 2d at 192; *Forman v. Novartis Pharmas. Corp.*, 794 F. Supp. 2d 382, 384 (E.D.N.Y. 2011) (finding methodology of reviewing certain regulatory filings, internal documents, and medical literature, then applying the relevant FDA regulations and procedures to it is reliable and permitted to render opinions on the reasonableness of a defendant's conduct).

Accordingly, Dr. Pence's methodology is reliable and does not, in any way, run afoul of the admissibility criteria espoused by the Supreme Court in *Daubert*. Because Dr. Pence's methodology is reliable and accepted, her testimony should be admitted.

VI. Dr. Pence's Opinion that Ethicon did not act in the interest of patient safety is relevant and reliable.

Ethicon states that the entire premise of this opinion is faulty because the decision to stop selling products did not constitute recalls of the products, nor was it mandated by the FDA. This is not a premise of Dr. Pence's opinion; Dr. Pence has merely opined that the available evidence supports that the device should have been removed from the market sooner. Dr. Pence's opinion that Ethicon should have acted more quickly to remove the Prosima from the market is rooted in

the development challenges and failures of the Prosima, detailed in her expert report, including the clinical evaluation of the prototype by the inventor, the marketing clearance of the device achieved with no clinical data submission, and the internal concerns voiced regarding the Prosima voiced by Ethicon employees and consultants once the device was launched, and the high number of MDR's reported to the FDA on the mesh used in the Prosima, the Gynemesh PS.[31]

Dr. Pence should be permitted to set forth the factual basis for her opinion that Ethicon had a duty that it failed to fulfill. For example, a medical device manufacturer's regulatory obligation to submit an MDR arises when the manufacturer gains awareness that a device may have caused or contributed to a death or serious injury. 21 CFR § 803.10; 803.20. It is therefore permissible for Dr. Pence to explain that Ethicon had received adverse event reports, as well as concerns from Ethicon's own employees and consultants, regarding concerns over the safety of the Prosima. Ethicon itself memorialized these as internal issue reports and memorandums. They provide a factual foundation for Dr. Pence's opinion that Ethicon should have known that the Prosima had an unfavorable risk profile and should have been removed it from the market sooner.

Thus, Dr. Pence appropriately set forth the documents and testimony demonstrating Ethicon's awareness of the Prosima risks, which then triggered Ethicon's obligation to remove the product from the market. Simply stated, no Ethicon credo or order from the FDA is necessary to conclude that Ethicon was aware of adverse event reports, the lack of clinical data, or of risks acknowledged by its researchers and executives. Ethicon's characterization of such evidence as an opinion regarding Ethicon's credo or internal policies is simply an effort to

[31] Def. Ex. E, Dr. Pence's Prosima report, Mar. 3, 2016, 19-21, 29, 31-32

hamstring Dr. Pence from referencing the factual support for her opinions. As such, Ethicon's argument should be denied.

CONCLUSION

For the reasons stated above, the Court should deny Defendants' motion and permit Dr. Pence's testimony to the extent stated in her reports. Dr. Pence is an extremely well qualified and knowledgeable expert who has devoted countless hours to the study of pelvic mesh products, and can still offer her opinions even if evidence of FDA clearance and other FDA actions is excluded by this court, as she relies on other standards in forming her opinions including the GHTF guidelines and industry standards. She should be permitted to give her opinions regarding the adequacy of the IFUs, the failure of testing, and the failure to meet the post-market vigilance standard of care for the Mesh Products.

Dated: May 9, 2016

Respectfully submitted,

/s/Thomas P. Cartmell
Thomas P. Cartmell, Esq.
Jeffrey M. Kuntz, Esp.
Wagstaff & Cartmell LLP
4740 Grand Avenue, Suite 300
Kansas City, MO 64112
816-701-1102
Fax 816-531-2372
tcartmell@wcllp.com
jkuntz@wcllp.com

/s/ D. Renee Baggett
Bryan F. Aylstock, Esq.
Renee Baggett, Esq.
Aylstock, Witkin, Kreis and Overholtz, PLC
17 East Main Street, Suite 200
Pensacola, Florida 32563

(850) 202-1010
(850) 916-7449 (fax)
rbaggett@awkolaw.com
baylstock@awkolaw.com

CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on May 9, 2015, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

/s/Thomas P. Cartmell
Attorney for Plaintiffs

INDEX OF EXHIBITS

Exhibit A: Device Labeling Guidance #G91-1 (blue book memo)

Exhibit B: Dr. Pence's CV

Exhibit C: Final Document: Global Harmonization Task Force. Essential principles of Safety and Performance of Medical Devices, November 2, 2012 (revision of GHTF/SG1/N41:2005).

Exhibit D: Transcript of Dr. David Robinson, March 14, 2012

Exhibit E: Transcript of Dr. Pence's January 1, 2013 Deposition

Exhibit F: Correspondence from FDA to Ethicon, August 10, 2007

Exhibit G: TVT IFU, released April, 2015

Exhibit H: Motion in Limine 5 and 9, *Batiste v. McNabb,* No. DC-12-14350.

Exhibit I: Order (transcript) Granting Motions in Limine 5 and 9 *Batiste v. McNabb,* No. DC-12-14350

Exhibit J: Ulatowski,TA., Risk Management: A Regulatory Perspective, Presentation, Beijing, October 2008